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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,520	07/11/2003	Fangming Kong	AM101031	6583
25291	7590	12/08/2004	EXAMINER	
WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/618,520

Applicant(s)

KONG ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-8 are pending.
2. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement ; and as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, had possession of the claimed invention; nor to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As stated in the MPEP 2164.01(a) "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". The factors to be considered herein are those set forth as the In re Wands, 8 USPQ 2nd 1400 (1988) decision.

Nature of invention

The claim is drawn to process of preparing a compound selected from AW998 A-D comprising cultivating *Streptomyces* LL-AW998 or a *mutant* thereof.

The state of the art and predictability

The mutation of micro-organism is a high unpredictable process, therefore, the registration and maintenance of "original" viable strand for practicing the process is required. The availability and registration was properly made by applicants as disclosed on page 5-6. No description as to how the mutants can be obtained and in what way would such mutant still maintain the property as required for production of AW998 A-D. Were such mutation can produce the claimed product, what, how and availability of such mutant have not been described in the specification nor to the public.

The amount of guidance and working examples

It is well recognized in the fermentation art that the products of fermentation not only depend on the stand of micro-organism in the cultural media but also the other nutrients made available as well as the condition for fermentation. When cultural media and fermentation condition differ, different products will be produced. In the specification, no description can be found as to what range of variation can be imposed on the fermentation process in nutrients, temperature, aeration etc. as to maintain the production of the desired product AW998 A-D. In view of the lack of description and enablement for the broad scope as claimed, it is

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recommended that only LL-AW998 and the particularity of fermentation being description and enablement as disclosed on page 14, example 2, be incorporated in the claim.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(f) he did not himself invent the subject matter sought to be patented.

Claims 1-8 are rejected under 35 U.S.C. 102(f) as being anticipated by Kong and Carter J. antibiotics.

Please note that the instant claims and the Kong and Carter reference disclosed identical compounds made by fermentation of AW998 culture, having antibacterial property. The inventive entity and the reference are "different" but two are identical. Please note that in MPEP 2307.01 it was stated:

35 U.S.C. 102(f) does not require an inquiry into the relative dates of a reference and the application, and therefore may be applicable where subsections (a) and (e) are not available for references having an effective date subsequent to the effective date of the application being examined. However for a reference having a date later than the date of the application some evidence may exist that the subject matter of the reference was derived from the applicant in view of the relative dates. *Ex parte Kusko*, 215 USPQ 972, 974 (Bd. App. 1981) (The relative dates of the events are important in determining derivation; a publication dated more than a year after applicant's filing date that merely lists as literary coauthors individuals other than applicant is not the strong evidence needed to rebut a declaration by the applicant that he is the sole inventor.).

Applicants are urged to consult MPEP 2307.01 to provide evidence in resolving the issue.


4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Nov. 30, 2004


Celia Chang
Primary Examiner
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